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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------------|----------------|----------------------|-------------------------|------------------|--|
| 10/016,225 | 10/19/2001 | Jeffery D. Snell | A01P1068 | 3020 | |
| 36802 7 | 590 11/18/2004 | | EXAM | INER | |
| PACESETTER, INC. | | | SCHAETZLE, KENNEDY | | |
| 15900 VALLE | Y VIEW COURT | | | | |
| SYLMAR, CA 91392-9221 | | | ART UNIT | PAPER NUMBER | |
| | | | 3762 | 3762 | |
| | | | DATE MAN ED. 11/10/2004 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|---|--|-------------------|--|--|--|
| | 10/016,225 | SNELL, JEFFERY D. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Kennedy Schaetzle | 3762 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| 1)⊠ Responsive to communication(s) filed on 09 A | uaust 2004. | | | | |
| | · | | | | |
| 3) Since this application is in condition for allowa | / | | | | |
| Disposition of Claims | | | | | |
| 4) ⊠ Claim(s) 1-14 and 28-45 is/are pending in the 4a) Of the above claim(s) is/are withdra 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1,5,6,9-14 and 28 is/are rejected. 7) ⊠ Claim(s) 2-4,7,8 and 29-45 is/are objected to. 8) □ Claim(s) are subject to restriction and/o Application Papers 9) □ The specification is objected to by the Examine 10) ⊠ The drawing(s) filed on 19 October 2001 is/are | wn from consideration. or election requirement. er. e: a)⊠ accepted or b)□ objected | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | |
| 2) Notice of Praftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date | Paper No(s)/Mail Da | | | | |

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DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1, 9-14 and 28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lee (Pat. No. 6,574,511).

Regarding claim 1, Lee discloses a system for use with implantable cardiac stimulation devices comprising a plurality of programmers (see Fig. 2) operative to program operations of implantable cardiac stimulation devices (see Fig. 1) and to process information received from implantable cardiac stimulation devices; and a programmer backup system 36 coupled to the plurality of programmers and operative to backup and synchronize information used by the programmers. Collected data from the implants may be stored at a central location via the network, and data can be exchanged between programmers as per col. 6, lines 39-44, thus enabling backup of information. It should be noted that the examiner considers even a temporary backup of information (note col. 4, lines 53-64) to broadly represent a backup of information since this information must be received or stored in the central server before it can be deleted from the programmer/instrument. Further, whether one would delete the data in the

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programmer/instrument would depend on the amount of available storage space and the size of the data files needed to be stored. In any event, the backup of medical data at a central location is old and well known in the data storage arts. Such a feature prevents a catastrophic failure at the central server from wiping out important medical records and is critical to the integrity of any data storage system.

Regarding the use of a system operative to synchronize information, the remote server of Lee is operative to synchronize the information used by the programmers by ensuring that the most up-to-date software is loaded on each programmer (note for instance col. 5, lines 14-17). In its broadest sense, automatically informing one of the need to update software would in the examiner's opinion, constitute a programmer backup system operative to synchronize information --whether or not additional human intervention is necessary to complete the software update. In any event, the courts have long determined that making automatic a manual event is a matter of obvious design (note MPEP 2144.04, III and *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)).

Regarding claim 9, the examiner considers the device of Lee to backup and synchronize one or more of programmer software data and patient personal data as discussed above. In order for the system of Lee to allow a remote operator to access the data center and change program parameters (see col. 3, lines 17-32), the parameters must first be backed up in memory somewhere at the central site.

Regarding claim 10, the examiner considers it inherent that the programmer software data comprises programmer software for controlling the programmers.

Regarding claims 11, 13 and 14, because claim 9 does not require that all of the items listed therein be associated with the programmer backup system (only that one or more be), if the examiner finds at least one item in the prior art, then the discovery of further limitations on additional optional items such as expressed in claims 11, 13 and 14 is not required. In other words, if the claim recites a list of optional elements such as A, B, C or D, and if the examiner finds element A, then further limitations on elements B, C and D recited in subsequent claims do not affect the validity of the rejection since these elements are all still optional.

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Regarding claim 28, comments similar to those presented in the rejection of claim 1 apply here as well. The examiner considers the central server to merge data from multiple programmers such as shown in Fig. 2. The reason for creating merged data (i.e., for use by the programmers) is considered to be a statement of intended use.

Claim Rejections - 35 USC § 103

4. Claims 5, 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (Pat. No. 6,574,511).

Regarding claims 5 and 6, although Lee does not explicitly refer to the use of a browser system connected through the Internet for displaying and modifying information stored within the backup system, Lee does refer to the use of computers 38 for networking to the programmer backup system (see Fig. 3). Clearly use of the ubiquitous Internet browser to display, access and modify information remotely would have been considered a matter of obvious design. Such a network allows for easy access to data from a variety of platforms and locations. One can additionally consider each individual programmer to enable modification of data at the central server as per col. 4, lines 33-44. A programmer for all intensive purposes can simply be a general purpose computer with special programming, data communications capabilities and telemetry to access the implant as is known in the art.

With reference to claim 12, although Lee does not specifically disclose that the patient personal data comprises medical histories and patient contact information, the examiner takes Official Notice that the collection of such data in medical devices of the type discussed by Lee is old and well known in the art. The particular type of information stored may depend upon a number of patient dependent parameters such as patient medical condition and patient location, as well as FDA requirements such as discussed in col. 1, lines 37-60. Patient contact information, for example, may be inherently necessary in order to inform the patient of required checkups. Knowing the medical history of a patient would clearly be desirable from the standpoint of predicting future events and tailoring treatment to the individual. Those of ordinary skill in the art desiring to provide the most comprehensive monitoring and effective treatment possible,

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would have therefore seen the obviousness of including such information in the makeup of the patient's personal data profile.

Response to Amendment

5. The affidavit filed on August 9, 2004 under 37 CFR 1.131 is sufficient to overcome the Kirkpatrick et al. reference.

Allowable Subject Matter

6. Claims 2-4, 7, 8 and 29-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Concerning claim 2, the prior art of record does not appear to disclose a system which automatically merges information received from programmers and subsequently transmits the merged information back to the programmers. A similar comment applies to claims 29 and 33

Regarding claims 7 and 36, the selective synchronization of information from amongst programmers within a particular group is not disclosed in the prior art.

Regarding claims 8 and 37, the selective synchronization of only selected types of information stored within the programmers is not disclosed in the prior art.

Regarding claim 34, the use of a central system that is operative to transmit the recited merged information in one of the manners set forth is not disclosed by prior artisans.

Regarding claim 35, there is no suggestion to detect inconsistent information that cannot be merged automatically.

Regarding claim 38, prior artisans do not disclose the recited combination of the means for synchronizing and the means for selectively transmitting.

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Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS

November 12, 2004

KENNEDY SCHAETZLE